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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/04/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,553

Applicant(s)

LU ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-8,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-8,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Claims 1 and 5-8 encompassing the PL protein LPAP and the PDZ protein TIP1, and the species of hematopoietic cell, signal transduction and the motif of X-S/T-X2-V/I/L in Paper No. 12 filed 8-21-02, is acknowledged. The traversal is on the ground(s) that an election of a single member of a Markush group are few enough that a search can be made without undue burden. Applicant contends that the current claims are directed to a small subset of interactions between certain PDZ and PL proteins. This is not found persuasive because the claims recite 17 PL proteins and 19 PDZ proteins in a method of modulating a biological function of an endothelial cell or a hematopoietic cell comprising introducing into the cell an agent that inhibits the binding of a PDZ protein and a PL protein, which translates into close to 400 interactions. Since each protein has a unique structure and function, and in some cases the function is not known (LPAP), it would require an undue search burden not only in terms of art, but also in terms of enablement, to examine a method comprising all of the proteins recited in the instant claims as one group or even as distinct species.

Because no art was found, the species requirement has been withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

New corrected drawings are required in this application because of the reasons outlined in the attached Drawing Review. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES**A. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings

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should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

C. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-8 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of modulating a biological function of an endothelial cell or a hematopoietic cell comprising introducing into the cell an agent that inhibits the binding of a PDZ protein and a PL protein, wherein the PL protein is LPAP and the PDZ protein is TIP-1.

The specification discloses on pages 45-46 that LPAP is known to be a transmembrane protein expressed on resting B and T cells, and that the actual function of LPAP is unknown, though LPAP is believed to function in organizing the signaling of CD45, which is part of the T cell complex, and that studies have suggested that LPAP plays a role in regulation of lymphocyte expansion. The specification also discloses that Applicant has shown that LPAP binds to TIP-1, that TIP-1 is known to be expressed in T cells and to also bind CD95 (CD95 being pivotal in apoptosis). The specification further speculates that Tip-1/LAP binding might compete for TIP-1/CD95 binding, thus being involved in switching from T-cell proliferation to apoptosis.

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The specification does not disclose that either LPAP or TIP-1 is expressed in endothelial cells. Therefore, it would require undue experimentation for one of skill to modulate a biological function of an endothelial cell using the recited method without further guidance from the specification because it is not clear that LPAP or TIP-1 is expressed in endothelial cells.

The specification discloses on page 29 that the term "biological function" refers to a detectable biological activity normally carried out by the cell such as proliferation, cell activation, and signal transduction. As stated above, the specification also discloses on pages 45-46 that the function of LPAP is unknown. Therefore, it would require undue experimentation for one of skill who wanted to practice the claimed method, to predict which biological functions would be altered, or how any of said biological functions would be altered, in a method of modulating a biological function of an endothelial cell or a hematopoietic cell comprising introducing into the cell an agent that inhibits the binding of TIP-1 to LPAP, because the function of LPAP is not known.

Tables 2-4 of the specification indicate that a GST fusion protein comprising the PDZ domain 1 (amino acids 35-137) of TIP-1 binds a peptide with the sequence of VTAL, which corresponds to the 4 carboxy terminal amino acids of the PL protein LPAP. Table 6 discloses that PL motif for binding TIP-1 is X-S/T-X2-V/I/L, which is consistent with the carboxy terminal VTAL sequence found in the PL protein LPAP. However Table 6 also discloses that several ligands fitting this motif do not bind TIP-1. Therefore, there appears to be uncertainty regarding what PL sequences will bind TIP-1. In view of the uncertainty regarding the ability of a peptide which has said motif, to bind TIP-1, it would require undue experimentation for one of skill in the art to predict which agent, known and unknown, would be a mimetic of the carboxy terminus of the PL protein LPAP and would be effective in inhibiting the binding of LPAP to TIP-1, without further guidance from the instant specification. Similarly, in view of this uncertainty regarding the motif, it would require undue experimentation for one of skill in the art to ascertain that a peptide agent comprising at least the carboxy-terminus two or three residues of the PL protein LPAP would be effective in inhibiting the binding of LPAP to TIP-1, without further guidance from the instant specification, especially since the binding motif is disclosed to be at least 4 amino acids long. It is noted that the specification does not exemplify a method of modulating a biological function comprising introducing into the cell any agent that inhibits binding of the PDZ protein TIP-1 and the PL protein LPAP in the cell.

In view of the quantity of experimentation necessary to use the claimed invention, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue experimentation to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 5-8 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-8 and 16-17 are indefinite in their recitation of non-elected subject material.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
October 31, 2002


Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640